

Food and Drug Administration
Center for Food Safety and Applied Nutrition
Office of Special Nutritionals

ARMS#

13341



0 - FRONT

MEDWATCH

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

For VOLUNTARY reporting
by health professionals of adverse
events and product problems

CFSAN

CFSAN

Page of

FDA Use Only

File no.
sequence #

13341

96746

001

Form Approved: OMB No. 0910-0281 Expires: 3/31/96
See OMB statement on reverse

A. Patient information

1. Patient Identifier
2. Age at time of event: 48
3. Sex: ☒ female ☐ male
4. Weight: 144 lbs or kgs
Date of birth:

B. Adverse event or product problem

1. ☒ Adverse event and/or ☐ Product problem (e.g., defects/malfunctions)

2. Outcomes attributed to adverse event (check all that apply):
☐ death (m/day/yr)
☐ life-threatening
☐ hospitalization - initial or prolonged
☐ disability
☐ congenital anomaly
☒ required intervention to prevent permanent impairment/damage
☐ other:

3. Date of event (m/day/yr): 1-22-99
4. Date of this report (m/day/yr): 2-1-99

5. Describe event or problem

BEGAN SUPPLEMENT (ONE BEFORE MEALS) ON 1/18/99. BY LUNCH ON 1/21 EXPERIENCED EXTREME HYPERTENSION. DISCONTINUED USE. A.M. 1/22 WOKE WITH EXTREME LOSS OF MOTOR SKILLS TO RIGHT HAND AND WRIST. WENT TO EMERGENCY. BLOOD PRESSURE 193/104.

1/25 B/P 188/110 SLIGHT RETURN MOTOR SKILL
1/28 " 168/95 NO IMPROVEMENT "
2/1 " 155/96 95% "
I AM NOW ON ZIAL FOR BLOOD PRESSURE

6. Relevant tests/laboratory data, including dates

1/22 CAT SCAN - NO SIGN OF STROKE
1/22 BLOOD WORK UP
1/28 NECK MRI - NO PINCHED NERVE

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

PHYSICAL IN NOV '98 BLOOD PRESSURE WAS 124/82. ALL BLOOD WORK O.K. I SMOKE 1 to 1 1/2 packs per day AND DRINK SOCIALLY.

C. Suspect medication(s)

1. Name (give labeled strength & mlr/labeler, if known)
#1 METAFORM DIETARY SUPPLEMENT
#2 METACUTS

2. Dose, frequency & route used

#1 1 CAP, 3 X DAILY
#2 1-18-99 to 1-21-99

3. Therapy dates (if unknown, give duration) (m/day/yr)

4. Diagnosis for use (indication)

#1 WEIGHT LOSS
#2

5. Event abated after use stopped or dose reduced

#1 ☒ yes ☐ no ☐ doesn't apply
#2 ☐ yes ☐ no ☐ doesn't apply

6. Lot # (if known)

#1 WN1828A
#2

7. Exp. date (if known)

#1 06-01
#2

8. Event reappeared after reintroduction

#1 ☐ yes ☐ no ☒ doesn't apply
#2 ☐ yes ☐ no ☐ doesn't apply

9. NDC # (for product problems only)

10. Concomitant medical products and therapy dates (exclude treatment of event)

D. Suspect medical device

1. Brand name

2. Type of device

3. Manufacturer name & address

4. Operator of device

☐ health professional
☐ lay user/patient
☐ other:

6. Model

7. If implanted, give date (m/day/yr)

8. If explanted, give date (m/day/yr)

9. Device available for evaluation? (Do not send to FDA)

☐ yes ☐ no ☐ returned to manufacturer on (m/day/yr)

10. Concomitant medical products and therapy dates (exclude treatment of event)

000001

E. Reporter (see confidentiality section on back)

1. Name & address

phone #

2. Health professional?

☐ yes ☒ no

3. Occupation

MANAGER

5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box.

☐ manufacturer
☐ user facility
☐ distributor



Mail to: MEDWATCH
5600 Fishers Lane
Rockville, MD 20852-9787

or FAX to:
1-800-FDA-0178

FDA Form 3500

Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

FEB 2 1999 8:00

MEDWATCH
THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

HF-2

CTU 96746

Adverse Event Questionnaire

Complaint Number: 13341 (96746)Investigator: John Lloyd

Consumer Information

Date of Report: _____

MM/DD/YY

Initial Report Source: ☐ORA Consumer Injury☐Telephone ☐Correspondence ☒MedWatch
☐USP ☐PQRS ☐Poison Control ☐CDC

Name: _____

Gender: ☒F ☐MAge: 48Race: ☒1-White ☐2-Black ☐3-Asian/Pacific Islander ☐4-Native American ☐5-Hispanic
☐8-Other ☐9-Unknown

Information on Adverse Event

Date of Adverse Event: 1-22-99

Previous Adverse Effects to Product Type:

☐Yes ☒NoGive the site of consumption/ingestion (e.g. home, restaurant, office): Home

The following information relates to the consumers' use of the product.

Describe the adverse event (including symptoms and the time lapse from using product to onset of symptoms):

BEGAN TAKING ON 1/18/99. 1/21/99 VERY HYPER DISCONTINUED USE. 1/22/99 EXTREME LOSS OF MOTOR SKILLS TO RIGHT ARM AND HAND. EXTREME BLOOD PRESSURE. REGAINED ARM USE
How long did the symptoms last? 2/4/99. STILL ON BLOOD PRESSURE MEDICINE.
Give the circumstances of exposure (i.e. how much was taken, how was the product taken, how often was it taken, etc.). 1 CAPSULE BEFORE EACH MEAL.

List all Medication(s), Dietary Supplement(s), Food(s), and other product(s) used at the time of the event:

BIRTH CONTROL

Did event abate after use of suspected product stopped or dose reduced: ☐Yes ☐No ☒UnknownDid symptoms reoccur after reintroduction of suspected product: ☐Yes ☐No ☐Unknown ☒Not ApplicableDid symptoms reoccur after using other products with the same ingredients: ☐Yes ☐No ☐Unknown ☒Not Applicable

Medical Information

Was a health care provider seen?: ☒Yes ☐No

Give health care provider's name, address and telephone number: _____

Occupation of Health Care Provider: ☒MD ☐Osteopath ☐Naturopath ☒Nurse ☐Pharmacist
☐Other (specify) _____

What medical tests were performed and what were the results?

CAT SCAN - NO STROKE
MRI - NO PINCHED NERVE
BLOOD WORKWhat was the medical diagnosis? ?What treatment(s) was given (e.g., drugs, other)? ZIAC BLOOD PRESSURE PILLS

Were there any preexisting condition(s)/treatment(s)?

(If YES, list them including allergies, and chronic diseases): ☐Yes ☒NoIN NOV. '98
BP WAS 124/82

000002

ATL # 90232

CF SAN # 13341

4/21/99 JAL.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

Memorandum

Date: April 21, 1999


From: John D. Lloyd, CSO ATL-DO

Subject: ATL Assignment #90232/CFSAN f/u #13341

To: Mallory W. Lawrence, SCSO ATL-DO

I have provided with this memo the documents requested by CFSAN under ATL-DO assignment # 90232. The original assignment was modified by CFSAN after the consumer elected not to release her medical record.

These documents are associated with an adverse event report, which CFSAN is researching.


John D. Lloyd


E N D O R S E M E N T

TO: Barbara A. Wood, Acting Director Investigations Br./ATL-DO

Date: 4/23/99

This investigation was conducted in follow-up to the request of Bridgette Wallace, CFSAN/HFS-636.

The subject, Ms. [REDACTED] took a food supplement called Metaform Dietary Supplement Metacuts. She subsequently suffered from extreme hypertension and the loss of motor skills in her right arm and hand. The food supplement is suspected of being responsible for her medical problems.


Mallory W. Lawrence, Supervisory Investigator
ATL-DO

O+Attachmt.: ATL-DO
cc+Attachmt.: CFSAN; HFS-636 (Attn.: Bridgette Wallace)
cc: ATL-DO/Consumer Complaint Coordinator
cc: MWL

000003

